with behenic acid accounting for about 42 percent.

Although the percentages of fatty acids in these two oils are different from that in glyceryl behenate, the types of fatty acids in the three oils are the same because they are all derived from fully hydrogenated rapeseed oil. The only difference among these oils is in the relative proportions of the fatty acids. Furthermore, because superglycerinated fully hydrogenated rapeseed oil and glyceryl behenate have similar percentage distributions of mono-, di-, and triglycerides, they have similar physical properties. Based on the similarity between glyceryl behenate and fully hydrogenated rapeseed oil and superglycerinated fully hydrogenated rapeseed oil and on its review of the information in GRAS petition 4G0036, FDA concludes that the information that supports the GRAS status of the use of the latter two substances can be relied upon in deciding whether the petitioned use of glyceryl behenate is GRAS.

Conclusions

The agency has evaluated all the information in the petition along with other available information that relates to the petitioned use of glyceryl behenate and has reached the following conclusions:

1. Glyceryl behenate is not GRAS based upon history of common use in food.

2. Glyceryl behenate is safe for use in tablets based on FDA's evaluation of information on the manufacturing process, the chemical composition, the estimated consumer exposure, and the toxicity of glyceryl behenate, fully hydrogenated rapeseed oil, and superglycerinated fully hydrogenated rapeseed oil.

3. Glyceryl behenate is GRAS based on scientific procedures. Glyceryl behenate is as safe as fully hydrogenated rapeseed oil and superglycerinated fully hydrogenated rapeseed oil. As noted above, glyceryl behenate has a similar percentage distribution of mono-, di-, and triglycerides as that in superglycerinated fully hydrogenated rapeseed oil and is composed of glycerides of the same fatty acids as those found in fully hydrogenated rapeseed oil and superglycerinated fully hydrogenated rapeseed oil. FDA affirmed that the use of the latter two oils is GRAS on the basis of scientific procedures (42 FR 48335 September 23, 1977). FDA is affirming that the use of glyceryl behenate as a formulation aid is GRAS on the basis of this material's similarity in composition to these oils.

4. Like other fatty acid glycerides, glyceryl behenate is effective for use in excipient formulations.

5. The material affirmed as GRAS is food-grade glyceryl behenate conforming to the identity and specifications set forth in the regulation below.

Therefore, the agency is affirming that when done in accordance with good manufacturing conditions, the use of glyceryl behenate as a formulation aid in excipient formulations for tablets is GRAS under § 184.1(b)(1). The agency is including the technical effect and food use in the regulation to make clear that the affirmation of the GRAS status of this material is based on the evaluation of limited uses.

Environmental Effects

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Economic Effects

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this rule would have on small entities including small businesses and has determined that the effect of this final rule is to provide a new use for glyceryl behenate. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, the economic effects of this rule have been analyzed, and FDA has determined that the rule is not a major rule as defined by that order. A copy of the threshold assessment supporting this determination is on file with the Dockets Management Branch (address above).

List of Subjects in 21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

2. Part 184 is amended by adding new § 184.1328 to read as follows:

§ 184.1328 Glyceryl behenate.

(a) Glyceryl behenate is a mixture of glyceryl esters of behenic acid made from glycerin and behenic acid (a saturated C_{22} fatty acid). The mixture contains predominantly glyceryl dibehenate.

(b) The ingredient meets the following specifications:

(1) 10 to 20 percent monoglyceride, 47 to 59 percent diglyceride, 26 to 38 percent triglyceride, not more than 1 percent free glycerin, and not more than 2.5 percent free fatty acids.

(2) Behenic acid. Between 80 and 90 percent of the total fatty acid content.

(3) Acid value. Not more than 4.

(4) Saponification value. Between 145 and 165.

(5) Iodine number. Not more than 3.

(6) Heavy metals (as Pb). Not more than 10 parts per million.

(c) In accordance with § 184.1(b)(1) of this chapter, the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient is generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid, as defined in § 170.3(o)(14) of this chapter.

(2) The ingredient is used in excipient formulations for use in tablets at levels not to exceed good manufacturing practice.

Dated: October 30, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–25583 Filed 11–4–87; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Parts 430, 436, and 442

[Docket No. 87N-0317]

Antibiotic Drugs; Cefuroxime Axetil Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the inclusion of accepted standards for a new dosage form of cefuroxime, cefuroxime axetil tablets. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective November 5, 1987; comments, notice of participation, and request for hearing by December 7, 1987; data, information, and analyses to justify a hearing by January 4, 1988.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFN-815), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new dosage form of cefuroxime, cefuroxime axetil tablets. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended in 21 CFR Parts 430, 436, and 442 to provide for the inclusion of accepted standards for the product.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, notice and comment procedure and delayed effective date are found to be unnecessary and not in the public interest. The final rule, therefore, is effective November 5, 1987. However, interested persons may on or before December 7, 1987, submit written comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before December 7, 1987, a written notice of participation and request for hearing, and (2) on or before January 4, 1988, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this order and filed in the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 430

Administrative practice and procedure, Antibiotics.

21 CFR Part 436

Antibiotics.

21 CFR Part 442

Antibiotics.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Parts 430, 436, and 442 are amended as follows:

PART 430—ANTIBIOTIC DRUGS; GENERAL

1. The authority citation for 21 CFR Part 430 continues to read as follows:

Authority: Secs. 507, 701(a), 59 Stat. 463 as amended, 52 Stat. 1055 (21 U.S.C. 357, 371(a)); 21 CFR 5.10.

2. Part 430 is amended in § 430.5 by adding new paragraphs (a)(91) and (b)(93) to read as follows:

§ 430.5 Definitions of master and working standards.

(a) * * *

(91) *Cefuroxime axetil.* The term "cefuroxime axetil master standard" means a specific lot of cefuroxime axetil that is designated by the Commissioner as the standard of comparison in determining the potency of the cefuroxime axetil working standard.

(b) * * *

(93) *Cefuroxime axetil.* The term "cefuroxime axetil working standard" means a specific lot of a homogeneous preparation of cefuroxime axetil.

3. In § 430.6 by adding new paragraph (b)(93) to read as follows:

§ 430.6 Definitions of the terms "unit" and "microgram" as applied to antibiotic substances.

* * * * *

(b) * * *

(93) *Cefuroxime axetil.* The term "microgram" applied to cefuroxime axetil means the cefuroxime activity (potency) contained in 1.246 micrograms of the cefuroxime axetil master standard.

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

4. The authority citation for 21 CFR Part 436 continues to read as follows:

Authority: Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357); 21 CFR 5.10.

5. Part 463 is amended in § 436.215 by alphabetically inserting a new item into the table in paragraph (b) and by adding new paragraph (c)(9) to read as follows:

§ 1436.215 Dissolution test.

* * * * *

(b) * * *

Dosage form	Dissolution medium	Rotation rate [1]	Sampling time(s)	Apparatus
*	*	*	*	*
Cefuroxime axetil tablets.	900 mL 0.07*N* hydrochloric acid.	55	15 min. and 45 min.	2
*	*	*	*	*

[1] Rotation rate of basket or paddle stirring element (revolutions per minute)

(c) * * *

(9) *Cefuroxime axetil*—(i) *Preparation of working standard solution.* Accurately weight approximately 60 milligrams of cefuroxime axetil working standard into a suitable-sized volumetric flask. Dissolve in 5 milliliters of methanol and dilute to volume with 0.07*N* hydrochloric acid. Further dilute with 0.07*N* hydrochloric acid to obtain a known concentration equivalent to 0.01 to 0.02 milligram of cefuroxime activity per milliliter.

(ii) *Preparation of sample solution.* Filter the sample through a 0.45-micrometer filter and dilute an accurately measured portion of the filtrate with sufficient 0.07*N* hydrochloric acid to obtain a concentration equivalent to 0.01 to 0.02 milligram of cefuroxime activity per milliliter (estimated).

(iii) *Procedure.* Using a suitable spectrophotometer and 0.07*N* hydrochloric acid as the blank, determine the absorbance of each standard and sample solution at the absorbance peak at approximately 278 nanometers. Determine the exact position of the absorption peak for the particular instrument used.

(iv) *Calculation.* Determine the total amount of cefuroxime activity dissolved as follows:

$$T = \frac{A_u \times c \times d \times 900}{A_s}$$

where:

T = Total milligrams of cefuroxime activity dissolved;

A_u = Absorbance of sample;

c = Cefuroxime activity of working standard solution in milligrams per milliliter;

d = Dilution factor of sample filtrate; and

A_s = Absorbance of standard.

6. By adding a new § 436.217 to read as follows:

§ 436.217 Film-coat rupture test.

(a) *Immersion fluid.* Dilute 6.0 milliliters of hydrochloric acid to 1,000 milliliters with water. During the performance of the test maintain the immersion fluid at a temperature of 37±0.5 °C by using a thermostatically controlled water bath.

(b) *Immersion vessel.* Use a suitable vessel, such as a 1-liter beaker.

(c) *Operation.* Add 750 milliliters of immersion fluid to the immersion vessel.

(d) *Procedure.* Drop a tablet into the immersion fluid and record the time for the tablet coat to rupture. Repeat the test with a further 19 tablets, testing not more than 10 tablets with a given volume of immersion fluid.

(e) *Evaluation.* The tablets pass the film-coat rupture test if the mean coat rupture time does not exceed 20 seconds and not more than 2 tablets have a coat rupture time exceeding 40 seconds.

PART 442—CEPHA ANTIBIOTIC DRUGS

7. The authority citation for 21 CFR Part 442 continues to read as follows:

Authority: Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357); 21 CFR 5.10.

8. Part 442 is amended by adding a new § 442.19 to read as follows:

§ 442.19 Cefuroxime axetial.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cefuroxime axetil is an amorphous mixture of the diastereoisomers of 5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[[(aminocarbonyl)oxy]methyl]-7-[[2-furanyl(methoxyimino)acetyl]amino]-8-oxo-, 1-(acetyloxy)ethyl ester, [6*R*-[6 *alpha*, 7 *beta* (*Z*)]]-. It is so purified and dried that:

(i) Its potency is not less than 745 micrograms and not more than 875 micrograms of cefuroxime per milligram on an anhydrous basis. The ratio of isomer A to total isomer content is not less than 0.48 and not more than 0.55.

(ii) Its moisture content is not more than 1.5 percent.

(iii) It is amorphous and not crystalline.

(iv) It passes the identity test.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Request for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for cefuroxime potency, isomer A ratio, moisture, crystallinity, and identity.

(ii) Samples, if required by the Director, Center for Drugs and Biologics: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.216 of this chapter, using ambient temperature, an ultraviolet detection system operating at a wavelength of 278 nanometers, a 25-centimeter by 4.6-millimeter column packed with methyl silane bonded silica 5 micrometers in particle size, a flow rate of 1 milliliter per minute, and a known injection volume of 10 microliters. Reagents, working standard and sample solutions, system suitability requirements, and calculations are as follows:

(i) *Reagents*—(A) *0.2M Ammonium phosphate solution.* Transfer 23.0 grams ammonium dihydrogen phosphate to a 1-liter volumetric flask. Dissolve and dilute to volume with distilled water. Mix well.

(B) *Mobile phase.* Transfer 380 milliliters of methanol to a 1-liter volumetric flask and dilute to volume with 0.2*M* ammonium phosphate solution.

(C) *Internal standard solution.* Prepare a solution containing 5.4 milligrams of acetanilide per milliliter in methanol.

(D) *System suitability test solution.* Mix 10.0 milliliters of a solution containing 1.2 milligrams of cefuroxime axetil working standard per milliliter in methanol with 5.0 milliliters of internal standard solution, 2.0 milliliters of a solution containing 0.3 milligram of an authentic sample of (*RS*)-1-acetoxyethyl (6*R*, 7*R*)-3-carbamoyloxymethyl-7-[(2′*Z*)-2-(fur-2-yl)-2-methyoxy-iminoacetamindo]ceph-2-em-4-carboxylate (delta-2 isomers of cefuroxime axetil) per milliliter in methanol and 1.8 milliliters of methanol. Dilute to 50 milliliters with 0.2*M* ammonium phosphate solution.

(ii) *Preparation of working standard and sample solutions*—(A) *Working standard solution.* Dissolve approximately 30 milligrams of the cefuroxime axetil working standard, accurately weighed, in methanol and dilute to 25 milliliters with methanol. Immediately transfer 10.0 milliliters of the working standard solution to a 50-milliliter volumetric flask. Add 5.0 milliliters of internal standard solution and 3.8 milliliters of methanol, and dilute to volume with 0.2*M* ammonium phosphate soluton to obtain a solution containing 0.2 milligram of cefuroxime

activity per milliliter. Store the solution under refrigeration no more than 8 hours.

(B) *Sample solution.* Dissolve approximately 30 milligrams of the sample, accurately weighed, in methanol and dilute to 25 milliliters with methanol. Immediately transfer 10.0 milliliters of the sample solution to a 50-milliliter volumetric flask. Add 5.0 milliliters of internal standard solution and 3.8 milliliters of methanol, and dilute to volume with 0.2*M* ammonium phosphate solution to obtain a solution containing 0.2 milligram of cefuroxime activity per milliliter (estimated). Store the solution under refrigeration no more than 8 hours.

(iii) *System suitability requirements*—(A) *Tailing factor.* The tailing factor (*T*) is satisfactory for isomer A if it is not more than 1.5 at 5 percent of peak height.

(B) *Efficiency of the column.* The efficiency of the column (*n*) is satisfactory for isomer A if it is greater than 3,000 theoretical plates.

(C) *Resolution.* The resolution (*R*) between isomer A and isomer B of cefuroxime axetil is satisfactory if it is not less than 1.5 and the resolution (*R*) between isomer A and the delta-2 isomers of cefuroxime axetil is satisfactory if it is not less than 1.5.

(D) *Coefficent of variation.* The coefficient of variation (S_R in percent) of five replicate injections is satisfactory if it is not more than 2.0 percent. If the system suitability requirements have been met, then proceed as described in § 436.216(b) of this chapter. Alternate chromatographic conditions are acceptable provided reproducibility and resolution are comparable to the system. However, the sample preparation described in paragraph (b)(1)(ii)(B) of this section should not be changed.

(iv) *Calculations*—(A) Calculate the micrograms of cefuroxime per milligram of sample as follows:

$$\text{Micrograms of cefuroxime per milligram} = \frac{R_u \times P_s \times 100}{R_s \times C_u \times (100 - m)}$$

where:

R_u = Sum of the peak height of the cefuroxime axetil sample isomer A and isomer B peaks/Peak height of the internal standard;

R_s = Sum of the peak heights of the cefuroxime axetil working standard isomer A and isomer B peaks/Peak height of the internal standard;

P_s = Cefuroxime activity in the cefuroxime axetil working standard solution in micrograms per milliliter;

C_u = Milligrams of sample per milliliter of sample solution; and

m = Percent moisture content of the sample.

(B) Calculate the ratio of isomer A to total isomer content as follows:

$$\text{Ratio of isomer A to isomer content} = \frac{\text{Peak height of the isomer A peak}}{\text{Peak area of the isomer A peak} + \text{peak area of the isomer B peak}}$$

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter, using the titration procedure described in paragraph (e)(1) of that section.

(3) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter, except that the particles do not reveal the phenomena of birefringence and extinction positions on revolving the microscope stage.

(4) *Identity.* Proceed as directed in § 436.211 of this chapter, using the mineral oil mull prepared as described in paragraph (b)(2) of that section.

9. By adding new § 422.119 to read as follows:

§ 442.119 Cefuroxime axetil tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cefuroxime axetil tablets are composed of cefuroxime axetil and one or more suitable and harmless diluents, binders, lubricants, and colorings. Each tablet contains 125 milligrams, 250 milligrams, or 500 milligrams of cefuroxime activity. Its potency is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of cefuroxime activity that it is represented to contain. Its moisture content is not more than 2.0 percent at the time of certification and not more than 6.0 percent at the time of expiry. It passes the dissolution test. It passes the film-coat rupture test. It passes the identity test. The cefuroxime axetil used conforms to the standards prescribed by § 442.19(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The cefuroxime axetil used in making the batch for potency, isomer A ratio, moisture, crystallinity, and identity.

(B) The batch for potency, moisture, dissolution, film-coat rupture, and identity.

(ii) Samples, if required by the Director, Center for Drugs and Biologics:

(A) The cefuroxime axetil used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch: A minimum of 100 tablets.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 442.19(b)(1). Working standard and sample solutions, system suitability requirements, and calculations are as follows:

(i) *Preparation of working standard and sample solutions*—(A) *Working standard solution.* Dissolve approximately 30 milligrams of the cefuroxime axetil working standard, accurately weighed, in methanol and dilute to 25 milliliters. Transfer 10.0 milliliters of the working standard solution to a 50-milliliter volumetric flask. Add 5.0 milliliters of internal standard solution, 3.8 milliliters of methanol, and dilute to volume with 0.2*M* ammonium phosphate solution to obtain a stock solution containing 0.24 milligram of cefuroxime axetil per milliliter. Store the stock solution under refrigeration no more than 8 hours.

(B) *Sample solution.* Grind a representative number of tablets in a mortar and pestle. Immediately swirl the ground tablets in a volumetric flask containing methanol and shake for 10 minutes to dissolve the ground cefuroxime axetil. Dilute with methanol to give a stock solution of convenient concentration. Filter the stock solution. Transfer 5.0 milliliters of filtrate to a 50-milliliter volumetric flask. Add 5.0 milliliters of internal standard solution and 8.8 milliliters of methanol. Dilute to volume with 0.2*M* ammonium phosphate solution. Store in a refrigerator and use within 8 hours.

(ii) *System suitability requirements*—(A) *Tailing factor.* The tailing factor (*T*) is satisfactory for isomer A if it is not more than 1.5 at 5 percent of peak height.

(B) *Efficiency of the column.* The efficiency of the column (*n*) is satisfactory for isomer A if it is greater than 3,000 theoretical plates.

(C) *Resolution.* The resolution (*R*) between isomer A and isomer B of cefuroxime axetil is satisfactory if it is not less than 1.5 and the resolution (*R*) between isomer A and the delta-2 isomers of cefuroxime axetil is satisfactory if it is not less than 1.5.

(D) *Coefficient of variation.* The coefficient of variation (S_R in percent) of five replicate injections is not more than 2.0 percent. If the system suitability requirements have been met, then proceed as described in § 436.216(b) of this chapter. Alternate chromatographic conditions are acceptable provided reproducibility and resolution are comparable to the system. However, the sample preparation described in paragraph (b)(1)(i)(B) of this section should not be changed.

(iii) *Calculation.* Calculate the cefuroxime content as follows:

$$\text{Milligrams of cefuroxime per tablet} = \frac{R_u \times P_s \times X}{R_s \times n}$$

where:

R_u = Sum of peak heights of the cefuroxime axetil sample isomer A and isomer B peaks/Peak height of the internal standard;

R_s = Sum of the peak heights of the cefuroxime axetil working standard isomer A and isomer B peaks/Peak height of the internal standard;

P_s = Potency of the cefuroxime axetil working standard in milligrams of cefuroxime activity per milliliter;

d = Dilution factor of the sample; and

n = Number of tablets in the sample assayed.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter, using the titration procedure described in paragraph (e)(1) of that section.

(3) *Dissolution.* Proceed as directed in § 436.215 of this chapter. The quantity Q (the amount of cefuroxime activity dissolved) is 60 percent at 15 minutes and 75 percent at 45 minutes.

(4) *Film-coat rupture test.* Proceed as directed in § 436.217 of this chapter.

(5) *Identity.* The high-performance liquid chromatogram of the sample solution determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the cefuroxime axetil working standard solution.

Dated: October 29, 1987.

Sammie R. Young,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 87-25584 Filed 11-4-87; 8:45 am]

BILLING CODE 4160-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[AD-FRL-3287-2]

Standards of Performance for New Stationary Sources; Grain Elevators and Stationary Gas Turbines; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: This notice clarifies the applicability dates for the standards of performance for grain elevators (Subpart DD of 40 CFR Part 60, published in the **Federal Register** August 3, 1978), and stationary gas turbines (Subpart GG of 40 CFR Part 60, published in the **Federal Register** September 10, 1979). The applicability dates were inadvertently omitted from these subparts.

EFFECTIVE DATE: November 5, 1987.

FOR FURTHER INFORMATION CONTACT: Doug Bell or Amanda Aldridge, Standards Development Branch, ESED (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone (919) 541-5568 or (919) 541-5268.

SUPPLEMENTARY INFORMATION:

List of Subjects in 40 CFR Part 60

Air pollution control.

Date: October 28, 1987.

Don R. Clay,

Acting Assistant Administrator for Air and Radiation.

For the reasons set out in the preamble, Title 40, Chapter I of the Code of Federal Regulations is amended as follows:

PART 60—[AMENDED]

1. The authority citation for Part 60 continues to read as follows:

Authority: Sections 101, 111, 114, 301(a), Clean Air Act as amended (42 U.S.C. 7401, 7411, 7414, 7601(a)).

2. By revising paragraph (b) of § 60.300 of Subpart DD—*Standards of Performance for Grain Elevators* to read as follows:

§ 60.300 Applicability and designation of affected facility.

* * * * *

(b) Any facility under paragraph (a) of this section which commences construction, modification, or reconstruction after August 3, 1978, is subject to the requirements of this part.

3. In Subpart GG—*Standards of Performance for Stationary Gas Turbines,* § 60.330 is revised (existing paragraph is designated as paragraph (a) and revised, and new paragraph (b) is added) as follows:

§ 60.330 Applicability and designation of affected facility.

(a) The provisions of this subpart are applicable to the following affected facilities: All stationary gas turbines with a heat input at peak load equal to or greater than 10.7 gigajoules per hour, based on the lower heating value of the fuel fired.

(b) Any facility under paragraph (a) of this section which commences construction, modification, or reconstruction after October 3, 1977, is subject to the requirements of this part except as provided in paragraphs (e) and (j) of § 60.332.

[FR Doc. 87-25539 Filed 11-4-87; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 403

[FRL-3287-1]

General Pretreatment Regulation for Existing and New Sources; Removal Credits

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: On April 30, 1986, the United States Court of Appeals for the Third Circuit invalidated certain portions of the amendments to the removal credits regulation promulgated on August 3, 1984 (49 FR 31212). *Natural Resources Defense Council, Inc.* v. *EPA,* 790 F.2d 289 (3d Cir. 1986). The effect of that decision on the removal credits rule was to leave in effect the previously promulgated versions of the 1984 regulatory provisions invalidated by the court. The purpose of today's action is to amend the removal credit regulation so that it properly reflects the effect of the court's decision.

DATE: This regulation shall become effective November 5, 1987.

FOR FURTHER INFORMATION CONTACT: Craig Jakubowics, Permits Division (EN-336), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (202) 475-9533.

SUPPLEMENTARY INFORMATION: On August 3, 1984, EPA promulgated amendments to the removal credits regulation, 40 CFR 403.7 (49 FR 31212). These amendments modified in part the previous version of § 403.7 that EPA promulgated on January 28, 1981 (46 FR 9404). The 1981 regulation was upheld

by the U.S. Court of Appeals for the Third Circuit. *National Association of Metal Finishers* v. *EPA*, 719 F.2d 624, 646–50 (3rd. Cir. 1984).

On April 30, 1986, the Third Circuit held three provisions of the 1984 amendments to be invalid. *NRDC* v. *EPA, supra.* Further, the Court held that EPA may not authorize removal credits in the absence of a more comprehensive set of sludge regulations under Section 405 of the Act.

The effect of the Third Circuit's invalidation of three provisions of the removal credits amendments is to leave in effect the 1981 versions of those three provisions. Thus, the current status of the removal credits regulation is:

(1) Portions of the 1984 amendments not invalidated by the Third Circuit remain in effect, and

(2) The 1981 versions of the three invalidated regulatory provisions are in effect.

Since the currently published version of 40 CFR 403.7 (1986) does not accurately reflect the current status of the removal credits regulation in the wake of the Third Circuit's decision, EPA is publishing today the revised versions of the three provisions that correspond to the current regulatory status as outlined above. Specifically, today's rule:

(1) Replaces the 1984 "consistent removal" provision (§ 403.7(b)) with the previous 1981 version (formerly § 403.7 (a)(2) and (b)(2)), now contained in § 403.7(b);

(2) Reinserts the 1981 definition of "Overflow" and the "compensation for overflow" provisions that had been deleted in the 1984 amendments (formerly § 403.7 (a)(3) and (b)(3), respectively), now contained in § 403.7(h); and

(3) Replaces the 1984 "modification on withdrawal of removal credits" provision (§ 403.7(f)(4)) with the previous 1981 version (formerly § 403.7(f)(5)), now contained in § 403.7(f)(4). The 1981 version of § 403.7(f)(4) is itself revised to delete references to "significant contribution", which was previously held illegal by the Third Circuit in *NAMF* v. *EPA*, supra, 719 F.2d at 638–41.

EPA is publishing these rules in final form. There is no need to solicit public comment on this rule, as it does not modify the current status of the removal credits regulation. Rather, it merely codifies the regulations currently in effect as the result of the Third Circuit's decision. For the same reasons, this regulation is effective immediately upon publication in the **Federal Register.**

Promulgation of this rule does not in itself entitle EPA to authorize removal credits. EPA must still comply with the Third Circuit's ruling requiring a more comprehensive set of sludge regulations under section 405 of the Act as a precondition for granting removal credits. EPA is working to comply with that ruling and will be proposing an extensive set of sludge guidelines under the authority of section 405(d). Note that section 406(e) of the Water Quality Act of 1987 provides that the Third Circuit decision as to sludge was stayed, but only until August 31, 1987, with respect to:

(1) Publicly owned treatment works (POTWs), the owner or operator of which received removal credits authority before February 4, 1987; and

(2) POTWs, the owner or operator of which submitted an application for removal credits authority which was pending on February 4, 1987, and was approved before August 31, 1987.

Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. Today's action does not satisfy any of the criteria specified in section 1(b) of the Executive Order. Therefore, it is not a major rulemaking. This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

Regulatory Flexibility Analysis

Today's action announces the current status of the removal credits regulation. Accordingly, I hereby certify, pursuant to 5 U.S.C. 605(b), that this action will not have a significant impact on a substantial number of small entities.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. 30501 *et seq.*, EPA must submit a copy of any rule that contains a collection of information requirement to the Director of the Office of Management and Budget for review and approval. This action contains no additional information collection requirements, and therefore the Paperwork Reduction Act is not applicable.

List of Subjects in 40 CFR Part 403

Confidential business information, Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control.

Dated: October 28, 1987.

A. James Barnes,

Acting Administrator.

PART 403—GENERAL PRETREATMENT REGULATIONS FOR EXISTING AND NEW SOURCES

For the reasons set out in the preamble, 40 CFR Part 403 is amended as follows:

1. The authority citation for Part 403 continues to read as follows:

Authority: Sec. 54(c) of the Clean Water Act of 1977 (Pub. L. 95–217); sections 204(b)(1)(C); 208(b)(2)(C)(iii); 301(b)(1)(A)(ii); 301(b)(2)(A)(ii); (301)(b)(2)(C); 301(h)(5); 301(i)(2); 304(e); 304(g); 307; 308; 309; 402(b); 405 and 501(e) of the Federal Water Pollution Control Act (Pub. L. 92–500), as amended by the Clean Water Act of 1977.

2. Section 403.7 is amended by revising paragraphs (b) and (f)(4) and by adding paragraph (h) to read as follows:

§ 403.7 Removal credits.

* * * * *

(b) *Establishment of Removal Credits; Demonstration of Consistent Removal.* (1) *Definition of Consistent Removal.* "Consistent Removal" shall mean the average of the lowest 50 percent of the removal measured according to paragraph (b)(2) of this section. All sample data obtained for the measured pollutant during the time period prescribed in paragraph (b)(2) of this section must be reported and used in computing Consistent Removal. If a substance is measurable in the influent but not in the effluent, the effluent level may be assumed to be the limit of measurement, and those data may be used by the POTW at its discretion and subject to approval by the Approval Authority. If the substance is not measurable in the influent, the date may not be used. Where the number of samples with concentrations equal to or above the limit of measurement is between 8 and 12, the average of the lowest 6 removals shall be used. If there are less than 8 samples with concentrations equal to or above the limit of measurement, the Approval Authority may approve alternate means for demonstrating Consistent Removal. The term "measurement" refers to the ability of the analytical method or protocol to quantify as well as identify the presence of the substance in question.

(2) *Consistent Removal Data.* Influent and effluent operational data demonstrating Consistent Removal or other information, as provided for in paragraph (b)(1) of this section, which demonstrates Consistent Removal of the

pollutants for which discharge limit revisions are proposed. This data shall meet the following requirements:

(i) *Representative Data; Seasonal.* The data shall be representative of yearly and seasonal conditions to which the POTW is subjected for each pollutant for which a discharge limit revision is proposed.

(ii) *Representative Data; Quality and Quantity.* The data shall be representative of the quality and quantity of normal effluent and influent flow if such data can be obtained. If such data are unobtainable, alternate data or information may be presented for approval to demonstrate Consistent Removal as provided for in paragraph (b)(1) of this section.

(iii) *Sampling Procedures: Composite.* (A) The influent and effluent operational data shall be obtained through 24-hour flow-proportional composite samples. Sampling may be done manually or automatically, and discretely or continuously. For discrete sampling, at least 12 aliquots shall be composited. Discrete sampling may be flow-proportioned either by varying the time interval between each aliquot or the volume of each aliquot. All composites must be flow-proportional to each stream flow at time of collection of influent aliquot or to the total influent flow since the previous influent aliquot. Volatile pollutant aliquots must be combined in the laboratory immediately before analysis.

(B)(1) Twelve samples shall be taken at approximately equal intervals throughout one full year. Sampling must be evenly distributed over the days of the week so as to include no-workdays as well as workdays. If the Approval Authority determines that this schedule will not be most representative of the actual operation of the POTW Treatment Plant, an alternative sampling schedule will be approved.

(2) In addition, upon the Approval Authority's concurrence, a POTW may utilize an historical data base amassed prior to the effective data of this section provide that such data otherwise meet the requirements of this paragraph. In order for the historical data base to be approved it must present a statistically valid description of daily, weekly and seasonal sewage treatment plant loadings and performance for at least one year.

(C) Effluent sample collection need not be delayed to compensate for hydraulic detention unless the POTW elects to include detention time compensation or unless the Approval Authority requires detention time compensation. The Approval Authority may require that each effluent sample be taken approximately one detention time later than the corresponding influent sample when failure to do so would result in an unrepresentative portrayal of actual POTW operation. The detention period is to be based on a 24-hour average daily flow value. The average daily flow used will be based upon the average of the daily flows during the same month of the previous year.

(iv) *Sampling Procedures: Grab.* Where composite sampling is not an appropriate sampling technique, a grab sample(s) shall be taken to obtain influent and effluent operational data. Collection of influent grab samples should precede collection of effluent samples by approximately one detention period. The detention period is to be based on a 24-hour average daily flow value. The average daily flow used will be based upon the average of the daily flows during the same month of the previous year. Grab samples will be required, for example, where the parameters being evaluated are those, such as cyanide and phenol, which may not be held for any extended period because of biological, chemical or physical interactions which take place after sample collection and affect the results. A grab sample is an individual sample collected over a period of time not exceeding 15 minutes.

(v) *Analytical methods.* The sampling referred to in paragraphs (b)(2) (i) through (iv) of this section and an analysis of these samples shall be performed in accordance with the techniques prescribed in 40 CFR Part 136 and amendments thereto. Where 40 CFR Part 136 does not contain sampling or analytical techniques for the pollutant in question, or where the Administrator determines that the Part 136 sampling and analytical techniques are inappropriate for the pollutant in question, sampling and analysis shall be performed using validated analytical methods or any other applicable sampling and analytical procedures, including procedures suggested by the POTW or other parties, approved by the Administrator.

(vi) *Calculation of removal.* All data acquired under the provisions of this section must be submitted to the Approval Authority. Removal for a specific pollutant shall be determined either, for each sample, by measuring the difference between the concentrations of the pollutant in the influent and effluent of the POTW and expressing the difference as a percent of the influent concentration, or, where such data cannot be obtained, Removal may be demonstrated using other data or procedures subject to concurrence by the Approval Authority as provided for in paragraph (b)(1) of this section.

* * * * *

(f) * * *

(4) *Modification or withdrawal of removal credits.*—(i) *Notice of POTW.* The Approval Authority shall notify the POTW if, on the basis of pollutant removal capability reports received pursuant to paragraph (f)(3) of this section or other relevant information available to it, the Approval Authority determines:

(A) That one or more of the discharge limit revisions made by the POTW, of the POTW itself, no longer meets the requirements of this section, or

(B) That such discharge limit revisions are causing a violation of any conditions or limits contained in the POTW's NPDES Permit.

(ii) *Corrective action.* If appropriate corrective action is not taken within a reasonable time, not to exceed 60 days unless the POTW or the affected Industrial Users demonstrate that a longer time period is reasonably necessary to undertake the appropriate corrective action, the Approval Authority shall either withdraw such discharge limits or require modifications in the revised discharge limits.

(iii) *Public notice of withdrawal or modification.* The Approval Authority shall not withdraw or modify revised discharge limits unless it shall first have notified the POTW and all Industrial Users to whom revised discharge limits have been applied, and made public, in writing, the reasons for such withdrawal or modification, and an opportunity is provided for a hearing. Following such notice and withdrawal or modification, all Industrial Users to whom revised discharge limits had been applied, shall be subject to the modified discharge limits or the discharge limits prescribed in the applicable categorical Pretreatment Standards, as appropriate, and shall achieve compliance with such limits within a reasonable time (not to exceed the period of time prescribed in the applicable categorical Pretreatment Standard(s) as may be specified by the Approval Authority.

* * * * *

(h) *Compensation for overflow.* "Overflow" means the intentional or unintentional diversion of flow from the POTW before the POTW Treatment Plant. POTWs which at least once annually Overflow untreated wastewater to receiving waters may claims Consistent Removal of a pollutant only by complying with either paragraph (h)(1) of (h)(2) or this section. However, this subsection shall not apply

where Industrial User(s) can demonstrate that Overflow does not occur between the Industrial User(s) and the POTW Treatment Plant;

(1) The Industrial User provides containment or otherwise ceases or reduces Discharges from the regulated processes which contain the pollutant for which an allowance is requested during all circumstances in which an Overflow event can reasonably be expected to occur at the POTW or at a sewer to which the Industrial User is connected. Discharges must cease or be reduced, or pretreatment must be increased, to the extent necessary to compensate for the removal not being provided by the POTW. Allowances under this provision will only be granted where the POTW submits to the Approval Authority evidence that:

(i) All Industrial Users to which the POTW proposes to apply this provision have demonstrated the ability to contain or otherwise cease or reduce, during circumstances in which an Overflow event can reasonably be expected to occur, Discharges from the regulated processes which contain pollutants for which an allowance is requested;

(ii) The POTW has identified circumstances in which an Overflow event can reasonably be expected to occur, and has a notification or other viable plan to insure that Industrial Users will learn of an impending Overflow in sufficient time to contain, cease or reduce Discharging to prevent untreated Overflows from occurring. The POTW must also demonstrate that it will monitor and verify the data required in paragraph (h)(1)(iii) of this section, to insure that Industrial Users are containing, ceasing or reducing operations during POTW System Overflow; and

(iii) All Industrial Users to which the POTW proposes to apply this provision have demonstrated the ability and commitment to collect and make available, upon request by the POTW, State Director or EPA Regional Administrator, daily flow reports or other data sufficient to demonstrate that all Discharges from regulated processes containing the pollutant for which the allowance is requested were contained, reduced or otherwise ceased, as appropriate, during all circumstances in which an Overflow event was reasonably expected to occur; or

(2)(i) The Consistent Removal claimed is reduced pursuant to the following equation:

$$r_c = r_m \frac{8760 - Z}{8760}$$

Where:

r_m = POTW's Consistent Removal rate for that pollutant as established under paragraphs (a)(1) and (b)(2) of this section

r_c = removal corrected by the Overflow factor

Z = hours per year that Overflow occurred between the Industrial User(s) and the POTW Treatment Plant, the hours either to be shown in the POTW's current NPDES permit application or the hours, as demonstrated by verifiable techniques, that a particular Industrial User's Discharge Overflows between the Industrial User and the POTW Treatment Plant; and

(ii) After July 1, 1983, Consistent Removal may be claimed only where efforts to correct the conditions resulting in untreated Discharges by the POTW are underway in accordance with the policy and procedures set forth in "PRM 75–34" or "Program Guidance Memorandum–61" (same document) published on December 16, 1975, by EPA Office of Water Program Operations (WH–546). (See Appendix A.) Revisions to discharge limits in categorical Pretreatment Standards may not be made where efforts have not been committed to by the POTW to minimize pollution from Overflows. At minimum, by July 1, 1983, the POTW must have completed the analysis required by PRM 75–34 and be making an effort to implement the plan.

(iii) If, by July 1, 1983, a POTW has begun the PRM 75–34 analysis but due to circumstances beyond its control has not completed it, Consistent Removal, subject to the approval of the Approval Authority, may continue to be claimed according to the formula in paragraph (h)(2)(i) of this section as long as the POTW acts in a timely fashion to complete the analysis and makes an effort to implement the non-structural cost-effective measures identified by the analysis; and so long as the POTW has expressed its willingness to apply, after completing the analysis, for a construction grant necessary to implement any other cost-effective Overflow controls identified in the analysis should Federal funds become available, so applies for such funds, and proceeds with the required construction in an expeditious manner. In addition, Consistent Removal may, subject to the approval of the Approval Authority, continue to be claimed according to the formula in paragraph (h)(2)(i) of this section where the POTW has completed and the Approval Authority has accepted the analysis required by PRM 75–34 and the POTW has requested inclusion in its NPDES permit of an acceptable compliance schedule providing for timely implementation of cost-effective measures identified in the analysis. (In considering what is timely implementation, the Approval Authority shall consider the availability of funds, cost of control measures, and seriousness of the water quality problem.)

[FR Doc. 87–25655 Filed 11–4–87; 8:45 am]
BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 0

[FCC 87–309]

Establishment of an Office of Public Affairs and an Office of Legislative Affairs

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This action reorganizes the Office of Congressional and Public Affairs into two independent offices: the Office of Public Affairs and the Office of Legislative Affairs.

EFFECTIVE DATE: October 13, 1987.

ADDRESS: Federal Communications Commission, 1919 M Street NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Walker Feaster, telephone: 202–632–3906.

SUPPLEMENTARY INFORMATION:

Adopted: September 22, 1987.

Released: October 27, 1987.

1. By this Order, the Commission amends its rules to reorganize the Office of Congressional and Public Affairs (OCPA) into two independent offices: the Office of Public Affairs (OPA) and the Office of Legislative Affairs (OLA).

2. The Commission's communication and liaison activities with the public, news media and the Congress were consolidated into one office in 1985. This reorganization was designed to create an integrated structure for disseminating the Commission's policies to these organizations and groups and to reflect an increasing commitment by the Commission to coordinate telecommunications policy with the Congress.[1] Experience with this

[1] Order Establishing the Office of Congressional and Public Affairs, 50 FR 2985 (January 23, 1985).